UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,211	02/13/2004	Markku Anttila	13601-072	2487

757 7590 04/30/2008
BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,211	ANTTILA, MARKKU	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **3/2/07** presents remarks and arguments to the office action mailed **11/02/06**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' argument's have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/16/07 is acknowledged and has been reviewed.

Status of claims:

Claims 1-5 and 7-13 are pending. Claims 10-13 are newly added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

> The claims recite geometric isomer stereoisomer and metabolites thereof but fail to show what these geometric isomer, steroisomer and metabolites are. Please note that metabolites when absorbed into the organism either breaks down into small simple particles or form a more complex molecule. As to isomers it is understood that the compound will have the same molecular formula but different chemical structures. These are not taught in the specification and one skilled in the art would not readily arrive at the same chemical structure for the various isomers.

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. In particular, Applicant has not provided a description of the structure of a representative number of derivative compounds nor a description of the chemical and/or physical characteristics of a representative number of compounds nor a description of how to obtain a representative number of specific compounds.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996)

(a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Maintained Claim Rejections - 35 USC § 103.

Applicant argues that Antilla (1997) Europ. J. Cancer, discloses that toremefene can be taken equally well in fasted conditions or with meals, and that the reference teaches away from the presence of a food effect for a tripheylethylene such as opemifene. Also that the absorption rate is 2-3 times higher than in fasted food as the unexpected result.

In response, the effect of food on drugs is well known in the art as early as 1978, this is not a new concept. Yes, some medications are taken on an empty stomach and some with food. These are all standard procedures of the drug before it gets to the consumer. See for example as evidence by Melander et al, wherein food intake of a drug had an increase of 85% when food was ingested. See entire Summary.
As to the evidence of Antila, it's taken into consideration in part, however, Applicant has failed to show how under the same condition as Applicants' claimed invention the absorption of toemifene, ospemifene and N-demethyltoremifene behaved under the conditions as claimed.

Claims 1-5 and 7-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Biskobing Expert Opinion Invest. Drug (of record) taken with of WO 97/32574 (of record) in view of Halonen et al. US 6,245,819(of record) further in view of

Vasu, Council of Medical Research 2000 (of record) and Melander et al. (newl) , Eur. J. Clinical Pharmcology 1978, 14, 441-444 as evidence by famildoc.org (of record).

Biskobing teaches administering the drug ospemifene (see abstract) to treat bone loss however, fails to teach treating skin atrophy.

WO teaches the same compound, structurally identical to that of the claimed subject matter, therefore a Z-isomer as required by instant claims 10-13. See page 1, lines 13-19 and abstract. With regards to the effective amount as required by instant claims 10-13, see page 3 lines 5-7. The reference also teaches the compound can be taken with other active compounds. Thus food is can be active agent as it comprises nutrients for the functioning of the body.

Halonen et al (US'819 hereafter) teaches FC127a(=deaminohydroxytoremifene) as well as active metabolites, geometric isomers or stereoisomers thereof, (see col. 2 lines 35-59). US'819 teaches the said compound and its medical use in the treatment of vaginal dryness and sexual dysfunction, with a dosage amount of 30, 60 and 90 as required by instant claims 10-13 see abstract and col. 2, lines 61-65. Thus one of ordinary skill in the art would have been motivated to use FC1271a of the prior art to treat skin atrophy. The reference is silent of the teaching of food effect but does not rule out drug is administered with or without food.

Melander et al. teach administering the drug (dicoumarol) during eating and blood samples were collected at different intervals. See underlining pages 441 and 442.

It is noted that the bioavailability is not taught as claimed however, one of ordinary skill in the art would have been motivated to combine the teachings of biskobing with Melander and compare the rate of absorption of the drug with food as illustrated in the prior art. One skilled in the art would interpret food as active compounds because they contain proteins, fat, carbohydrates etc, therefore would be motivated to administer ospemifene with food. FDA(CDER) sets forth also guidance of food effect on bioavailability of drugs. One of ordinary skill in the art would have been motivated to combine the prior art and determine the food effect of a poorly. As stated already most drugs are taken with food in order to prevent the patient from feeling nausea, from vomiting or other symptoms related to taking medication on empty stomach. See also familydoc.org of record.

As taught by Vasu, the bioavailability of certain drugs is enhanced by food, especially drugs that are not readily absorbed orally, and further teaches that the presence of lipids stimulates bile secretion. See page 3.

Thus one of ordinary skill in the art would be motivated to administer a drug such as ospemifene with food based on the teaching of the prior art.

Maintained Double Patenting

The rejection of the above is maintained for the same reasons that the 103 rejection is maintained. In this instance Applicant allerging that the teaching of Antila is away from claimed invention is not persuasive. As evident by Melander et al, it would

have been obvious to one of ordinary skill in the art to check the bioavailabilty of food effect on drugs before administration.

Claims 1, 8-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent Application No. 11201098. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims require the compound-ospemifene isadministered for the treatment of skin atrophy. As evident by Vasu, drugs are known in the art to be administered with food. With regard to Applicant's arguing that the disclosure is to enhancing bioavailability will not change treating atrophy, because as soon as the drug is available treating will proceed.

Claims 1-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6984665. Although the conflicting claims are not identical, they are not patentably distinct from each other. As evident by Vasu, drugs are known in the art to be administered with food. With regard to Applicant's arguing that the disclosure is to enhancing bioavailability, as soon as the drug is bioavailable, treating skin atrophy will proceed.

Applicant argues that none of the applications or the patents applied in the rejections contains disclosure of enhancing bioavailability.

The scope as a whole is the same. Administering the drug with or without food is not going to change the mechanism of action of the drug in the system. Once the drug

gets in the system it is available to proceed with said treatment. It would have been reasonable to expect an efficacious treatment modality would occur following "enhanced" bioavailability of the compound –ospemifene.

Careful thought have been given to the remarks, but are found unpersuasive and the rejection is maintained as in the office action on record.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG

4/22/08

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614